

Claims:

1. A salt of 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione and phosphoric acid, or a solvate or a non solvated form thereof.
2. A salt as claimed in claim 1, being 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate wherein the molar ratio of 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione to phosphate is 1 : 1 , or a solvate or non-solvated form thereof.
3. A crystalline polymorph A of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate hydrate, characterised by an X-ray powder diffraction (XRPD) pattern having intensity peaks at values expressed in 2-theta degrees of about 15.63, 15.75, 17.30, 19.61 and 21.47.
4. A crystalline polymorph A of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate hydrate, characterised by an X-ray powder diffraction (XRPD) pattern substantially in accordance with Table 1 and Figure 1.
5. A crystalline polymorph A according to claim 3 or 4, being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate hydrate, characterised by an infrared spectrum with bands observed at 2704, 1748, 1701, 1643, 1611, 1546, 1513, 1469, 1420, 1391, 1330, 1302, 1244, 1110, 1028, 928, 821, 767, 716 cm⁻¹.
6. A crystalline polymorph B of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern having intensity peaks at values expressed in 2-theta degrees of about 4.19, 16.45, 17.01, 18.89 and 21.35.
7. A crystalline polymorph B of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate

characterised by an X-ray powder diffraction (XRPD) pattern substantially in accordance with Table 3 and Figure 5.

8. A crystalline polymorph B according to claim 6 or 7, being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate, characterised by an infrared spectrum with bands observed at 3050, 2875, 2455, 2325, 2165, 2141, 2114, 2051, 1982, 1874, 1750, 1697, 1640, 1611, 1546, 1513, 1464, 1441, 1416, 1393, 1366, 1333, 1318, 1301, 1284, 1244, 1219, 1181, 1161, 1114, 1097, 1081, 1044, 1030, 994, 948, 924, 896, 826, 812, 772, 741, 712 cm^{-1} .
9. A crystalline polymorph B1 of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern having intensity peaks at values expressed in 2-theta degrees of about 16.46, 19.51, 19.76, 19.88 and 23.31.
10. A crystalline polymorph B1 of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern substantially in accordance with Table 4 and Figure 7.
11. A crystalline polymorph B1 according to claim 9 or 10, being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate, characterised by an infrared spectrum with bands observed at 3050, 2875, 2455, 2325, 2165, 2141, 2114, 2051, 1982, 1874, 1750, 1697, 1640, 1611, 1546, 1513, 1464, 1441, 1416, 1393, 1366, 1333, 1318, 1301, 1284, 1244, 1219, 1181, 1161, 1114, 1097, 1081, 1044, 1030, 994, 948, 924, 896, 826, 812, 772, 741, 712 cm^{-1} .
12. A crystalline polymorph C of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate hydrate characterised by an X-ray powder diffraction (XRPD) pattern having intensity peaks at values expressed in 2-theta degrees of about 12.86, 15.98, 16.26, 21.60 and 24.50.

13. A crystalline polymorph C of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern substantially in accordance with Table 2 and Figure 3.
14. A crystalline polymorph C according to claim 12 or 13, being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate, characterised by an infrared spectrum with bands observed at 3111, 2924, 2652, 2325, 2165, 2114, 2051, 1981, 1874, 1745, 1698, 1641, 1608, 1541, 1513, 1464, 1443, 1416, 1392, 1363, 1332, 1301, 1265, 1249, 1218, 1179, 1163, 1113, 1096, 1048, 1028, 995, 951, 926, 905, 823, 812, 774, 739, 713 cm^{-1} .
15. A crystalline polymorph D of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern having intensity peaks at values expressed in 2-theta degrees of about 14.33, 16.05, 16.36, 21.97 and 22.89.
16. A crystalline polymorph D of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern substantially in accordance with Table 6 and Figure 10.
17. A crystalline polymorph D according to claim 15 or 16, being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate, characterised by an infrared spectrum with bands observed at 3129, 2933, 2684, 2325, 2165, 2150, 2113, 2051, 1982, 1743, 1699, 1641, 1604, 1538, 1511, 1467, 1446, 1412, 1389, 1357, 1332, 1303, 1279, 1242, 1164, 1107, 1077, 1063, 1021, 994, 956, 928, 903, 832, 802, 769, 739, 719 cm^{-1} .
18. A crystalline polymorph E of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern having intensity peaks at values expressed in 2-theta degrees of about 4.60, 13.39, 18.20, 18.53 and 22.75.

19. A crystalline polymorph E of a salt according to claim 1 or 2 being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate characterised by an X-ray powder diffraction (XRPD) pattern substantially in accordance with Table 5 and Figure 8.
20. A crystalline polymorph E according to claim 18 or 19, being a 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate, characterised by an infrared spectrum with bands observed at 2918, 2702, 2417, 2324, 2165, 2051, 1982, 1752, 1700, 1642, 1610, 1546, 1512, 1468, 1443, 1419, 1395, 1364, 1331, 1303, 1238, 1181, 1165, 1140, 1096, 1052, 1029, 1008, 953, 906, 882, 831, 819, 768, 739, 714, 663 cm^{-1} .
21. A compound according to any one of claims 1 to 20 in isolated form
22. A compound according to any one of claims 1 to 20 in substantially pure form
23. A process for preparing a salt according to claim 1 or 2, comprising reacting 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione or a salt thereof, dispersed or suspended or dissolved in a suitable solvent medium, with a suitable source of a phosphate ion.
24. A process for preparing a crystalline polymorph A, B, B1 or E, according to any one of claims 3 to 5, 6 to 8, 9 to 11, or 18 or 20, comprising reacting 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione or a salt thereof, dispersed or suspended or dissolved in a suitable solvent medium, with a suitable source of a phosphate ion, and thereafter, carrying out the following steps:
 - (i) optionally forming a solvate of the 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate,
 - (ii) recovering the 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl] methyl]-2,4-thiazolidinedione phosphate,
 - (iii) drying the 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate obtained in step ii), especially under vacuum, to obtain the 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate in its polymorphic form A, B, B1 or E.

25. A process according to claim 23 or 24, wherein the suitable source of the phosphate ion is phosphoric acid.
26. A process for preparing a crystalline polymorph C according to any one of claims 12 to 14, comprising the following steps:
- (i) dispersing or suspending or dissolving 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate in its polymorphic forms A, B, B1, D or E, in a suitable solvent medium to obtain a mixture,
 - (ii) stirring the mixture obtained in step (i) alternately for about 1 hour at about 50°C and subsequently for about 1 hour at about 10°C, for a total of about 3 to about 5 days,
 - (iii) recovering the product, i.e. polymorph C, from the mixture obtained in step (ii), and
 - (iv) air-drying the product obtained in step (iii).
27. A process for preparing a crystalline polymorph C according to any one of claims 12 to 14, comprising the following steps:
- (i) dissolving or dispersing or suspending 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate of Form A, B, B1, D or E in a suitable solvent medium to obtain a mixture,
 - (ii) adding a suitable source of a phosphate ion, e.g. phosphoric acid, to the mixture obtained in step (i),
 - (iii) recovering the product, i.e. polymorph C, from the mixture obtained in step (ii), and
 - (iv) air-drying the product obtained in step (iii).
28. A process according to claim 26 or 27, wherein the suitable solvent medium is a mixture of acetone and water.
29. A process for preparing crystalline polymorph D according to any one of claims 15 to 17, comprising the following steps:
- (i) dissolving or dispersing or suspending 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione phosphate in its polymorphic Form A in a suitable solvent medium to obtain a mixture,

- (ii) heating the mixture obtained in step (i) to a temperature of about 60°C for about 4 hours, followed by cooling the mixture to about room temperature under stirring,
 - (iii) recovering the product, i.e. polymorph D, from the mixture obtained in step (ii), and
 - (iv) drying the product obtained in step (iii), preferably in vacuo.
30. A process according to claim 29, wherein the suitable solvent medium is methanol.
31. A compound according to any one of claims 1 to 14 and 18 to 20, or a mixture thereof, for use as a medicament.
32. Use of a compound according to any one of claims 1 to 14 and 18 to 20, or of a mixture thereof, for the manufacture of a medicament for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof in a human or non-human mammal.
33. A pharmaceutical composition comprising a compound according to any one of claims 1 to 14 and 18 to 20, or a mixture thereof, and a pharmaceutically acceptable carrier.
34. A pharmaceutical composition comprising a compound as claimed in any one of claims 1 to 14 and 18 to 20, or a mixture thereof, in combination with one or more other anti-diabetic agents, and a pharmaceutically acceptable carrier.
35. A method for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof which comprises administering a compound according to any one of claims 1 to 14 and 18 to 20, or a mixture thereof, to a human or non-human mammal in need thereof.
36. A method for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof which comprises administering a pharmaceutical composition according to claim 33 or 34 to a human or non-human mammal in need thereof.